

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Louis S. Crocker, et al.		
Serial No.:	10/660,936	Case: 21063DACB	Art Unit: 1625
Filed:	September 12, 2003		
For:	POLYMORPHIC, AMORPHOUS AND HYDRATED FORMS OF 5-CHLORO-3-(4- METHANESULFONYLPHENYL)-6'-METHYL- [2,3']BIPYRIDINYL		Examiner: Davis, Z.N.

Assistant Commissioner for Patents  
Washington, D.C. 20231

**DECLARATION OF LOUIS S. CROCKER**  
**PURSUANT TO 37 C.F.R. 1.131**

Sir:

I, Louis S. Crocker, hereby declare the following:

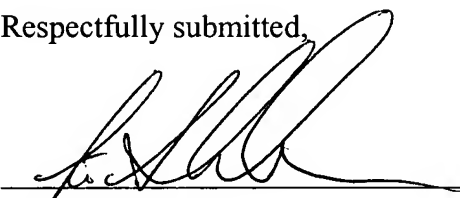
1. I was awarded a Bachelor's degree in 1983 by Middlebury College, Middlebury, Vermont.
2. I was awarded a Ph. D. degree in 1989 by Yale University, New Haven, Connecticut.
3. I am a joint inventor named in the referenced patent application.
4. I have been employed by Merck & Co., Inc. continuously since June, 1992 and currently hold the title of Senior Research Fellow in the Department of Analytical Research.

5. Attached hereto is a reproduction of a notebook entry (Merck Research Laboratories Notebook page 17538-74) made by me that I signed and dated prior to July 11, 1997. This entry describes several analyses that were performed on a sample of L-791,456 free base (the compound of Formula A as referred to in the above-referenced application). The particular analyses performed on the sample are XRPD (X-ray powder diffraction), TG (Thermogravimetric analysis), DSC (Differential scanning calorimetry), and Acid Titration. The result of the XRPD analysis is noted as "Crystalline material" and indicates that the X-ray powder diffraction pattern contained well-resolved peaks characteristic of crystalline material. The pattern of peaks observed in the noted XRPD pattern is characteristic of Form I and differs from patterns obtained from other crystalline phases of L-791,456 free base.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statement made of information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

3 Feb 2004  
Date

Respectfully submitted,

  
Louis S. Crocker

17538-  
74

Redacted



L-791,456 - Free base - Hartman

XRPD 45kW/40mA

single: L-791,456 free base, 24045-176, 9701673

file: V074a

Crystalline material.

TG 10°C/min, N<sub>2</sub>

single: 9701673

file: V074b

36°C to 171°C: 0.15 = 0.2% wt. loss  
wt. loss accompanies melting

DSC 10°C/min, N<sub>2</sub>, open pan

single: 9701673 (1.390g)

file: V074c

endotherm, extng. onset = 135.7°C, peak = 137.3°C, 72.9 J/g  
Sample appeared fused and slightly discolored after stopping  
run at approx. 150°C. N.B. The extrapolated onset  
temperature of the melting endotherm is usually  
associated with the melting point.

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Bas. Acid Titration file 24, 2199

0.1N HCl. No clear endpoint observed at the  
low pH's obtained in the vicinity of the expected  
endpoint. Sample of 22.760mg (B-25) undissolved  
in 5ml H<sub>2</sub>O, undiss. 5ml H<sub>2</sub>O + 2ml MeOH, dissolved  
in 5ml H<sub>2</sub>O + 5ml MeOH, titrated in this solvent.

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Countersigned

Richard Vassilakis

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